Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 306

Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902805 059700307 059302007	09/16/02 07/10/02 04/24/00	729 728 729	50 (1) 50 (1) 50 (1)	21(676) 25(680) 20(670)	506.2 510.4 484.2	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902805 059700307 059302007	09/17/02 07/11/02 04/24/00	730 729 731	50 (1) 50 (1) 50 (1)	19(646) 29(695) 30(672)	341.0 337.8 319.5	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 307

			Male				Female	
#All Organs: Benign Tumors								
-		49/50 (98%)	46/50 (92%)	47/50 (94%)		37/50 (74%)	46/50 (92%)	44/50 (88%)
Overall Incidence	Total	142/150 (94.67%)	Mean 94.67%	SD 3.06%	Total	127/150 (84.67%)	Mean 84.67%	SD 9.45%
#All Organs: Malignant Tumors		20/50 (529/)	22/50 (46%)	24/50 (000/)		40/50 (200/)	45/50 (200())	20/50 (448/)
Overall Incidence	Total	26/50 (52%) 83/150 (55.33%)	23/50 (46%) Mean 55.33%	34/50 (68%) SD 11.37%	Total	19/50 (38%) 56/150 (37.33%)	15/50 (30%) Mean 37.33%	22/50 (44%) SD 7.02%
		,				` ,		
#All Organs: Malignant and Benign Tu	umors							
Occupation of the second	T-1-1	49/50 (98%)	50/50 (100%)	50/50 (100%)	T-1-1	44/50 (88%)	48/50 (96%)	48/50 (96%)
Overall Incidence	Total	149/150 (99.33%)	Mean 99.33%	SD 1.15%	Total	140/150 (93.33%)	Mean 93.33%	SD 4.62%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
			•••••					
#All Organs: Hemangiosarcoma								
3		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
-	-	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Selected Control Animal Grou

Page: 308

Report Date:04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Mal	le				Female	
All Organs: Histiocytic Sarcoma			()							
			(2%)		(2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.	.33%)	Mean	1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
All Organs: Leukemia: Erythrocytic		0/50	(00()	0/50	(00/)	0/50 (00/)		0/50 (00()	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 0/150 (09	(0%) %)	0/50 (Mean	(0%) 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Leukemia: Lymphocytic, M Undifferentiated	Monocytic, M	lononuclear,	or			•••••				
		17/50	(34%)	17/50 ((34%)	13/50 (26%)		12/50 (24%)	10/50 (20%)	9/50 (18%)
Overall Incidence	Total	47/150 (3	31.33%)	Mean	31.33%	SD 4.62%	Total	31/150 (20.67%)	Mean 20.67%	SD 3.06%
All Organs:										
Malignant Lymphoma: His or Undifferentiated Cell Ty			(0%)	0/50 /	(0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
or Undifferentiated Cell Ty			(0%) .33%)	0/50 (Mean	(0%) 1.33%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
or Undifferentiated Cell Ty	/pe	0/50	` '	Mean	1.33%	` ,	Total	` ,	` ,	SD 0%
or Undifferentiated Cell Ty Overall Incidence #All Organs: Mesothelioma: Benign	/pe Total	0/50 2/150 (1.	(0%)	Mean	(2%)	SD 2.31% 		0/150 (0%) ´ 0/50 (0%)	Mean 0% /	SD 0% (0%)
or Undifferentiated Cell Ty Overall Incidence All Organs: Mesothelioma: Benign	Total Total	0/50 2/150 (1. 0/50 1/150 (0.	(0%)	1/50 (Mean	(2%) 0.67%	SD 2.31% 	Total	0/150 (0%) 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%) SD 0%
or Undifferentiated Cell Ty Overall Incidence #All Organs: Mesothelioma: Benign Overall Incidence	/pe Total Total	0/50 2/150 (1. 0/50 1/150 (0.	(0%)	1/50 (Mean	(2%) 0.67%	SD 2.31% 	Total	0/150 (0%) 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%) SD 0%
or Undifferentiated Cell Ty Overall Incidence #All Organs:	/pe Total Total	0/50 2/150 (1. 0/50 1/150 (0.	(0%)	Mean 1/50 (Mean	(2%) 0.67%	SD 2.31% 	Total	0/150 (0%) 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 309

			Male				Female	
#All Organs: Mesothelioma: Malignant		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma			0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Osteosarcoma		0/50 (00/)		0/50 (00)	•••••	0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		0/50 (00()	2/52 (00/)	0/50 /00/)		0/50 (00/)	0/50 (0%)	2/50 (00/)
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	3/50 (6%) Mean 2%	0/50 (0%) SD 3.46%	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%
*Adrenal Cortex: Carcinoma		0/50 (00/)		0/50 (00)	•••••	0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 310

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Hemangioma		0/50 (09/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/40 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma Beni	gn	2/50 (69/)	E/EO (400()	2/50 (69/)		1/50 (20/)	1/50 (29/)	0/40 (09/)
Overall Incidence	Total	3/50 (6%) 11/150 (7.33%)	5/50 (10%) Mean 7.33%	3/50 (6%) SD 2.31%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%
*Adrenal Medulla: Pheochromocytoma Com		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Mali	gnant							
Overall Incidence	Total	0/50 (0%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	4/50 (8%) SD 4.62%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma: Ben	ign, Comple		5/50 /400/	0/50 /400()		4/50 (00)	4/50 (00/)	0/40 (00/)
Overall Incidence	Total	3/50 (6%) 14/150 (9.33%)	5/50 (10%) Mean 9.33%	6/50 (12%) SD 3.06%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 311

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Bone: Chondrosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chondrosarcoma or Chond	Iroma	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Chordoma		0/50 (0%)	0/50 (0%)	0/50 (00)		0/50 (0%)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (09())	0/50 (00/)	0/50 /(0//)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: ETHANOL

r Selected Control Animal Groups

Route: SKIN

Report Date:04/29/2009

Page: 312

Species: RATS Strain: F344

Length of Study: CHRONIC

			Male	Female
*Brain: Astrocytoma Malignant	Tatal	0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%)
*Brain: Ependymoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Brain: Glioma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Brain: Granular Cell Tumor Benigi	n	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Brain: Medulloblastoma Mal	••••	0/50 (09/)	0/50 (00/) 0/50 (00/)	0/50 (09/) 0/50 (09/) 0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Control Animal Groups Report Date:04/29/2009

Page: 313

			Male				Female	
*Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Ma	alignant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
*Brain: Oligodendroglioma Ben	ign	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Mali	ignant	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Brain: Oligodendroglioma, Glid	oma, or Astroc	-	4/50 (004)	4/50 (00/)		4/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Brain: Osteosarcoma	•••••	0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 314

			Male	Female
*Brain: Schwannoma Malignant		(20)		
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Clitoral/Preputial Gland: Adenoma				
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) 1/50 (2%) Mean 3.33% SD 1.15%	2/50 (4%) 6/50 (12%) 2/50 (4%) Total 10/150 (6.67%) Mean 6.67% SD 4.62%
*Clitoral/Preputial Gland: Carcinoma				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 2/50 (4%) Total 2/150 (1.33%) Mean 1.33% SD 2.31%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		2/50 (4%)	2/50 (4%) 2/50 (4%)	2/50 (4%) 6/50 (12%) 4/50 (8%)
Overall Incidence	Total	6/150 (4%)	Mean 4% SD 0%	Total 12/150 (8%) Mean 8% SD 4%
*Clitoral/Preputial Gland: Fibrosarcoma				0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Clitoral/Preputial Gland: Sarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 315

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma	1	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Fibrosarcoma		0/50 (0%)	0/50 (09/)	0/50 (09/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Lipoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		4/50 (00)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Eye: Amelanotic Melanoma, Bo	enign							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Eye: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

r Selected Control Animal Group

Page: 316

Report Date:04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (09/)	0/50 (09/)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Heart: Schwannoma Benign		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
*Heart: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Intestine Large: Colon/Rectur Adenoma	n:							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date:04/29/2009 SKIN

Page: 317

			Male	Female
#Intestine Large: Colon/Rectum: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Large: Colon/Rectum: Carcinoma or Adenoma		0/50 (00()	0.50 (00)	4/50 (001) 4/50 (001) 0/50 (001)
Occupation of the sec	T-1-1	0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 2/150 (1.33%) Mean 1.33% SD 1.15%
#Intestine Large: Colon/Rectum: Hemangioma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Carcinoma				
	.	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Leiomyoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Jejunum: Carcinoma		0/50 (09/)	0/50 /0%) 0/50 /0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Tatal 0/450 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 318

			Male	Female
#Intestine Small: Jejunum: Granular Cell Tumor Malig	jnant			
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
·····			Widaii 6.0770 GD 1.1070	10tal 0/100 (070) INICAL 070 GD 070
#Intestine Small: Jejunum: Leiomyoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
			Wican 670 GB 670	10tal 0/100 (070) INCAN 070 0D 070
#Intestine Small: Jejunum: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Overall incluence	TOLAI	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Weath 0% 3D 0%
#Intestine Small: Site Unspeci Carcinoma	ified:	0/50 (00/)	0/50 (00)	0/50 (00%) 0/50 (00%) 0/50 (00%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
		,		
#Intestine Small: Site Unspeci Carcinoma or Adenoma	ified:			
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Overali incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspeci Granular Cell Tumor Malig				
Overell healthanes	Tatal	1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) T-t-1 0/450 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 319

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female			
#Intestine Small: Site Unspecified: Leiomyoma										
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Intestine Small: Site Unspecif Leiomyosarcoma	ied:				•••••	•••••		•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
slets, Pancreatic: Adenoma					•••••	•••••		•••••		
		3/50 (6%)	6/50 (12%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%		
slets, Pancreatic: Carcinoma					•••••	•••••		•••••		
		0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
slets, Pancreatic: Carcinoma or Adenoma					•••••	•••••		•••••		
		3/50 (6%)	6/50 (12%)	7/50 (14%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	16/150 (10.67%)	Mean 10.67%	SD 4.16%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
Kidney: Pelvis and Transition Carcinoma	al Epitheliu	m:			•••••					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 320

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale						Fem	ale	
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
	otal	0/150	,	Mean		SD		Total	0/150	,		n 0%	SD 0%
Kidney: Pelvis and Transitional Ep Papilloma		1:											•••••
		0/50	(0%)		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence T	otal	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD 0%
(idney: Renal Tubule: Adenoma		0/50	(204)		(004)		(004)		0/-0	(201)	- /	(224)	(201)
		0/50	(0%)		(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
	otal		(0.67%)		0.67%		1.15%	Total	0/150	,		n 0%	SD 0%
idney: Renal Tubule: Carcinoma													
		0/50	(0%)		(0%)	0/50	(0%)	-	0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence T	otal	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD 0%
idney: Renal Tubule: Carcinoma or Adenoma													
		0/50	(0%)		(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence T	otal	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mea	n 0%	SD 0%
idney: Renal Tubule: Hemangiosarcoma													
		0/50	(0%)		(0%)	0/50	(0%)	-	0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence T	otal	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 321

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ETHANOL

				Ма	ale						Fem	ale		
*Kidney: Renal Tubule: Lipoma														
Overall Incidence	Total	1/50 1/150	(2%) (0.67%)		(0%) 0.67%	0/50 SD	(0%) 1.15%	Total	0/50 0/150	(0%) (0%)	0/50 Mea	(0%) n 0%	0/50 SD	(0%) 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benign		0/50	(0%)	1/50	(2%)	0/50	(0%)	•••••	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total		(0.67%)		0.67%		1.15%	Total	0/30	` ,		n 0%	SD	` '
*Kidney: Renal Tubule: Nephroblastoma		0/50	(00/)	0/50	(00/)	0/50	(00/)		0/50	(00/)	0/50	(00/)	0/50	(00/)
Overall Incidence	Total	0/50	(0%) (0%)	0/50 Mean	(0%) 0%	0/50 SD	(0%) 0%	Total	0/50	(0%) (0%)	0/50 Mea	(0%) n 0%	0/50 SD	(0%) 0%
*Kidney: Renal Tubule: Sarcoma					(00()	0/50	(00()	•••••	4/50	(20/)	0/50	(00/)	0/50	(00/)
Overall Incidence	Total	0/50 0/150	(0%) (0%)	0/50 Mean	(0%) 0%	0/50 SD	(0%) 0%	Total	1/50 1/150	(2%) (0.67%)	0/50 Mea	(0%) n 0.67%	0/50 SD	(0%) 1.15%
*Liver: Cholangioma	• • • • • • • • • • • • • • • • • • • •	•••••				•••••								
Overall Incidence	Total	0/50 0/150	(0%) (0%)	0/50 Mean	(0%) 0%	0/50 SD	(0%) 0%	Total	0/50 0/150	(0%) (0%)	0/50 Mea	(0%) n 0%	0/50 SD	(0%) 0%
*Liver: Hemangiosarcoma		0/50	(00/)	0/50	(00()	0/50	(00/)	•••••	0/50	(00/)	0/50	(00/)	0/50	(00/)
Overall Incidence	Total	0/50 0/150	(0%) (0%)	0/50 Mean	(0%) 0%	0/50 SD	(0%) 0%	Total	0/50 0/150	(0%) (0%)	0/50 Mea	(0%) n 0%	0/50 SD	(0%) 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 322

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Liver: Hepatocellular Adenoma		0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (0%)	G/EQ (420()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 6/150 (4%)	0/50 (0%) Mean 4%	6/50 (12%) SD 6.93%
Liver: Hepatocellular Carcinom	a	0.50	(20)	(00)	•••••	(201)	(00)	(201)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Liver: Hepatocellular Carcinom	a or Hepatob		4/50 (001)	0/50 /00/)	•••••	0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Liver: Hepatocellular Carcinom	a or Hepatoc		4/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (0%)	C/FO (400/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 6/150 (4%)	0/50 (0%) Mean 4%	6/50 (12%) SD 6.93%
Liver: Hepatocellular Carcinom Hepatoblastoma	a, Hepatocell							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 6/150 (4%)	0/50 (0%) Mean 4%	6/50 (12%) SD 6.93%
Lung: Alveolar/Bronchiolar Ade	enoma	4/50 (00/)	4/50 (00)	4/50 (00/)	•••••	0/50 (00)	4/50 (00/)	0/50 /00()
Overall Incidence	Total	4/50 (8%) 6/150 (4%)	1/50 (2%) Mean 4%	1/50 (2%) SD 3.46%	Total	0/50 (0%) 4/150 (2.67%)	4/50 (8%) Mean 2.67%	0/50 (0%) SD 4.62%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

Page: 323

		Male				Female	
cinoma							
Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
cinoma or Alv	veolar/Bronchiolar						
	5/50 (10%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	4/50 (8%)	0/50 (0%)
Total	8/150 (5.33%)	Mean 5.33%	SD 4.16%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Total	` '	` '	` '	Total	` ,	, ,	0/50 (0%) SD 0%
Total	0/130 (0/8)	Weall 070	30 0%	Total	0/130 (0/8)	Mean 070	3D 070
	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
a	0/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 /00/	0/50 (00/)
Total	` ,	` ,	, ,	Total	` ,	` '	0/50 (0%) SD 0%
	Total Total Total Total Total	1/50 (2%) Total 2/150 (1.33%) Cinoma or Alveolar/Bronchiolar 5/50 (10%) Total 8/150 (5.33%) 0/50 (0%) Total 0/150 (0%) Total 0/150 (0%) Total 0/150 (0%) Total 0/50 (0%) Total 0/50 (0%)	Total 2/150 (2%) 1/50 (2%) Total 2/150 (1.33%) Mean 1.33% Cinoma or Alveolar/Bronchiolar 5/50 (10%) 2/50 (4%) Total 8/150 (5.33%) Mean 5.33% 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0%	1/50 (2%)	Cinoma 1/50 (2%) Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total Cinoma or Alveolar/Bronchiolar 5/50 (10%) Total 8/150 (5.33%) Mean 5.33% SD 4.16% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Total 1/50 (2%) Total 1/50 (2%) Total 7/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total	cinoma 1/50 (2%) 1/50 (2%) 0/50 (0%) Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 1/150 (0.67%) cinoma or Alveolar/Bronchiolar 5/50 (10%) 2/50 (4%) 1/50 (2%) 0/50 (0%) Total 8/150 (5.33%) Mean 5.33% SD 4.16% Total 4/150 (2.67%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)	Cinoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 1/50 (0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Control Animal Groups Report Date:04/29/2009
N

Page: 324

			Male				Female	
#Lymph Node: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Adenolipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (09/)
Overall Incidence	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Adenoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%
#Mammary Gland: Carcinoma or Adenoma		(20)	(00)	(201)	•••••	(00)	(00)	(00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 8/150 (5.33%)	3/50 (6%) Mean 5.33%	4/50 (8%) SD 3.06%
#Mammary Gland: Fibroadenoma		0/50 (00/)	4/50 (00)	0/50 (00)	•••••	40/50 (005)	44/50 (0000)	40/50 (040)
Overall Incidence	Total	3/50 (6%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	0/50 (0%) SD 3.06%	Total	16/50 (32%) 42/150 (28%)	14/50 (28%) Mean 28%	12/50 (24%) SD 4%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 325

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Mammary Gland: Fibroma								
• "' ''	-	0/50 (0%)	` '	/50 (0%)	.	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
Overall Incidence	Total	3/50 (6%)	(,	/50 (0%) SD 3.06%	Total	16/50 (32%)	15/50 (30%)	12/50 (24%) SD 4.16%
Overall incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.00%	Total	43/150 (28.67%)	Mean 28.67%	SD 4.10%
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, o							
		3/50 (6%)	(,	/50 (0%)		17/50 (34%)	17/50 (34%)	14/50 (28%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	48/150 (32%)	Mean 32%	SD 3.46%
#Mesentery: Fibrosarcoma		0/50 (0%)	0/50 (0%) 0/	/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50 (09/)	0/50 (0%) 0/	/FO (09/)		0/50 (09/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/ Mean 0%	/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mesentery: Lipoma								
Overell Incidence	Tatal	0/50 (0%)	` '	/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 326

Report Date:04/29/2009

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Mesentery: Rhabdomyosarcoma		0/50 (09/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Adenoma		2/22 (22)			•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Chondroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Squamous Cell Carcinoma	a	0/50 (004)	0/50 (00/)	4/50 (00)		0(10 (00))	0(50 (00))	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or P	ngue, Phary							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinoma	ngue, Phary							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 327

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male					Female				
Oral Cavity (Oral Mucosa, Tong Squamous Cell Carcinoma, I Papilloma		Squamous, or								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	3/50 (6%) SD 3.06%		
Oral Mucosa: Squamous Cell Carcinoma	•••••	0/50 (00()						4/50 (00/)		
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
Oral Mucosa: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
vary: Cystadenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%		
vary: Granulosa Cell Tumor Benig	n					0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%		
ovary: Granulosa Cell Tumor Malig	nant					4/50 (20/.)	0/50 (0%)	0/50 (0%)		
verall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 328

Report Date:04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
*Ovary: Granulosa Cell Tumor:	Benign, Malign	nant, NOS						
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Ovary: Granulosa-Theca Tumo					•••••			
Overall Incidence	, Doingi				Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary:								
Granulosa-Theca Tumo	or Malignant					0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenom	na							
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas:			•••••					
Adenoma		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 3.46%	Total	0/150 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 329

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Pancreas: Carcinoma or Adenoma				
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) 3/50 (6%) Mean 2% SD 3.46%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Malignant		0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Parathyroid Gland: Adenoma				0/43 (0%) 0/46 (0%) 0/45 (0%)
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) 0/49 (0%) Mean 0% SD 0%	0/43 (0%) 0/46 (0%) 0/45 (0%) Total 0/134 (0%) Mean 0% SD 0%
#Peripheral Nerve: Schwannoma Malignant			0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mali	gnant, NOS		0/50 (00/) 0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009 Vehicle: ETHANOL

Page: 330

			Male				Female		
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma									
		35/49 (71%)	32/50 (64%)	29/50 (58%)		22/50 (44%)	35/50 (70%)	33/50 (66%)	
overall Incidence	Total	96/149 (64.43%)	Mean 64.48%	SD 6.73%	Total	90/150 (60%)	Mean 60%	SD 14%	
Pituitary Gland: Pars Distal Carcinoma		fied Site:							
		0/49 (0%)	0/50 (0%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
verall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 5.77%	Total	3/150 (2%)	Mean 2%	SD 3.46%	
Pituitary Gland: Pars Distal		ied Site:							
Carcinoma or Adenoma		35/49 (71%)	32/50 (64%)	34/50 (68%)		22/50 (44%)	35/50 (70%)	36/50 (72%)	
verall Incidence	Total	101/149 (67.79%)	Mean 67.81%	SD 3.72%	Total	93/150 (62%)	Mean 62%	SD 15.62%	
		,				` ,			
Pituitary Gland: Pars Distal Ganglioneuroma	is or Unspecif	fied Site:							
_		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
ituitary Gland: Pars Intern	nedia:								
Adenoma									
		0/49 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
rituitary Gland: Pars Intern Carcinoma									
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 331

Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/49 (0%)(0%)(6%)(0%)(0%)**Overall Incidence** Total 3/149 (2.01%) Mean 2% SD 3.46% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Prostate: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** SD 1.15% Total 1/150 (0.67%) Mean 0.67% *Prostate: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)Overall Incidence Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Salivary Glands: Sarcoma 0/50 (0%)(0%)1/49 (2%)(0%)0/50 (0%)0/50 0/50 **Overall Incidence** Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 0/150 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle: Fibrous Histiocytoma** (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

Page: 332

		Male				Female	
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) (Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	1/50 (29/)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/30 (0%)	Mean 0%	SD 0%
			••••••				
Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) (Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
habdomyom	a		•••••				
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) (Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	Total Total Total Total	1/50 (2%) Total 1/150 (0.67%) 0/50 (0%) Total 1/150 (0.67%) 0/50 (0%) Total 0/150 (0%) Total 0/150 (0%) Total 0/150 (0%)	O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% 1/50 (2%) O/50 (0%) Total 1/150 (0.67%) Mean 0.67% O/50 (0%) O/50 (0%) Total 1/150 (0.67%) Mean 0.67% O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% nabdomyoma O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0%	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total 0/150 (0%) Mean 0% SD 0% 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) D/50 (0%) 0/50 (0%) Total 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total nabdomyoma 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total Total 0/150 (0%) Mean 0% SD 0% Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) 1/50 (2%) O/50 (0%) O/50 (0%) O/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total O/150 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total O/150 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total O/150 (0%) Total 0/150 (0%) Mean 0.67% SD 0% Total 1/150 (0.67%) nabdomyoma 0/50 (0%) 0/50 (0%) O/50 (0%) O/50 (0%) Total 1/150 (0.67%) Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%)	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) 0/50 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% Total 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% Total 0/150 (0%) 0/50 (0%) Mean 0.67% SD 0/50 (0%) Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 333

Report Date:04/29/2009

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male					Female				
Skin: Basal Cell Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 /00/	0/50 (00/)		
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Skin:	_					•••••				
Basal Cell Adenoma or	Basosquamou	•	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)		
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Skin: Basal Cell Adenoma, B Trichoepithelioma		Tumor Benign, or 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma o	or Basosquamo	ous Tumor (malignant o	r			•••••				
NOS)	-									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Basal Cell Carcinoma, I Tumor (benign, maligna		Trichoepithelioma	(201)				(201)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 334

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale					Female	
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 2/50 (4%) 2/50 (4%) 4/50 (8%) 0/50 (0%) 1/50 (2%) 1/50 (2%)										1/50 (2%)	
verall Incidence	Total	8/150 (5	` '		5.33%		2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Skin: Fibroma	•••••					•••••					
Overall Incidence	Total	1/50 13/150 ((2%) (8.67%)		(14%) 8.67%	5/50 SD	(10%) 6.11%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, My	xoma, M yxos 3/50 16/150 ((6%)		(16%) 10.67%	5/50 SD	(10%) 5.03%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Fibrosarcoma		······································									
Overall Incidence	Total	2/50 2/150 (1	(4%) .33%)		(0%) 1.33%	0/50 SD	(0%) 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin:										0/50 (00)	
Fibrosarcoma, Sarcoma, Histiocytoma		0/50	(40/)						0/50 (0%)	0/50 (0%)	0/50 (0%)
Histiocytoma	Total	2/50 3/150 (2	(4%) 2%)	1/50 Mean	(2%) 2%	0/50 SD	(0%) 2%	Total	0/150 (0%)	Mean 0%	SD 0%
		3/150 (2	2%)	Mean	2%	SD	2%		0/150 (0%) ´	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 335

			Male				Female	
#Skin: Hemangioma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall incluence	ı Olai	0/130 (0/8)	ivican 070		ı Olai	0/130 (0/8)	ivieaii 076	
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma		0/50 (004)	0/50 (404)			0/50 (00)	0/50 (00/)	4/50 (001)
Overall Incidence	Total	0/50 (0%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	3/50 (6%) SD 3.06%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Skin: Lipoma		0/50 (00/)	4/50 (00)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Liposarcoma		2/22 (201)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Vehicle: ETHANOL

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Page: 336 Report Date:04/29/2009

			Male				Female	
#Skin: Neural Crest Tumor, Mali	gnant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwan								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or Sc	:hwannoma (r	malignant or NOS) 1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Neurofibrosarcoma, Neur malignant or NOS)	rofibroma, or	Schwannoma (benign,						
Overall Incidence	Total	1/50 (2%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Skin: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Schwannoma Benign		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 337

Report Date:04/29/2009

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignant				-/		(00)	2/22 (221)	2/52 (194)
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) 2 Mean 2.67%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Skin: Squamous Cell Carcino	ma							
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) (Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Squamous Cell Carcino Basosquamous Tumor (0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Squamous Cell Papillom	na	0/50 (00/)	0/50 (00)	4/50 (00/)		0/50 (00/)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papillon	na or Papillom		0/50 (00)	4/50 (00/)		0/50 (004)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papillom Carcinoma or Keratoaca		Squamous Cell						
Overall Incidence	Total	1/50 (2%) 7/150 (4.67%)	2/50 (4%) 4 Mean 4.67%	4/50 (8%) SD 3.06%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 338

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female		
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
Overall Incidence	Total	0/50 (0%) 6/150 (4%)	2/50 (4%) Mean 4%	4/50 (8%) SD 4%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
#Skin: Trichoepithelioma		4/50 (20/)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Skin: Sebaceous Gland: Adenoma		0/50 (00/)	0/50 (00)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Skin: Sebaceous Gland: Carcinoma									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00)	4/50 (001)		0/50 (00)	0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Spinal Cord: Astrocytoma Benign		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

e: SKIN

Page: 339

Report Date:04/29/2009

Length of Study: CHRONIC

Route: SKIN Vehicle: ETHANOL

			Male				Female	
#Spinal Cord: Astrocytoma Malignant		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Fibrosarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Fibrous Histiocytoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma	•••••	0/50 (09/)	0/50 (09/)	0/50 (09/)		0/50 (/0%)	0/50 (09/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Hemangiosarcoma	•••••	0/50 (00()	0/50 (00/)	0/50 (0%)		0/50 (00)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 340

			Male				Female	
Spleen: Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 /00/3		
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Sarcoma		4/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach: Leiomyosarcoma		0/50 (004)						
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
tomach, Forestomach: Squamous Cell Carcinom		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
tomach, Forestomach: Squamous Cell Carcinom	a or Papillon		4/50 (004)	4/50 (004)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
tomach, Forestomach: Squamous Cell Papilloma								
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 341

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Glandular: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		30/50 (60%)	37/50 (74%)	36/50 (72%)				
Overall Incidence	Total	103/150 (68.67%)	Mean 68.67%	SD 7.57%				
*Thymus: Sarcoma		0/49 (0%)	0/49 (0%)	0/49 (0%)	•••••	0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/40 /09/\	0/40 (0%)	0/40 (09/)		0/49 (0%)	0/45 (09/)	0/50 (00/)
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 342

			Male	Female
*Thymus: Thymoma NOS		0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%) 0/45 (0%) 0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Thymus: Thymoma: Benign, Maligna	nt, NOS	0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%) 0/45 (0%) 0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Thyroid Gland: C-Cell: Adenoma	•••••	10/50 (20%)	10/50 (20%) 5/50 (10%)	6/50 (12%) 8/50 (16%) 3/50 (6%)
Overall Incidence	Total	25/150 (16.67%)	Mean 16.67% SD 5.77%	Total 17/150 (11.33%) Mean 11.33% SD 5.03%
*Thyroid Gland: C-Cell: Carcinoma		1/50 (2%)	2/50 (4%) 5/50 (10%)	0/50 (0%) 0/50 (0%) 2/50 (4%)
Overall Incidence	Total	1/50 (2%) 8/150 (5.33%)	2/50 (4%) 5/50 (10%) Mean 5.33% SD 4.16%	0/50 (0%) 0/50 (0%) 2/50 (4%) Total 2/150 (1.33%) Mean 1.33% SD 2.31%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	•••••			
Overall Incidence	Total	11/50 (22%) 33/150 (22%)	12/50 (24%) 10/50 (20%) Mean 22% SD 2%	6/50 (12%) 8/50 (16%) 5/50 (10%) Total 19/150 (12.67%) Mean 12.67% SD 3.06%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (0%)	0/50 /00/) 4/50 /00/)	4/50 (00) 0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 343

			Male				Female	
*Thyroid Gland: Follicular Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/50 (00/)	4/50 (00)	4/50 (00)		0/50 (40/)	0/50 (0%)	4/50 (00()
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
#Tissue NOS: Lipoma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS: Paraganglioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 /00/	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (/0//)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 /09/	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 344

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female			
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%		
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%		
#Tooth: Adamantinoma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00()		0/50 (00/)	0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
*Urinary Bladder: Carcinoma		0/50 (00/)	0/50 (00)	0/50 (004)	· · · · · · · · · · · · · · · · · · ·	0/50 (004)	0/50 (00)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Urinary Bladder: Carcinoma or Papilloma						2/22 (221)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 345

			Male				Female	
Urinary Bladder: Hemangiosarcoma		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (09/)	0/50 /00/
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
rinary Bladder: Leiomyosarcoma		0/50 (00/)						
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
rinary Bladder: Papilloma	•••••	0/50 (00/)	0/50 (00()	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (004)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
terus: Adenoma						0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
terus: Carcinoma	•••••							
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
terus: Deciduoma Benign								
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Vehicle: ETHANOL

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 346

	Male			Female	
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus:					
Leiomyosarcoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/30 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal				•••••	
Overall Incidence		Total	5/50 (10%) 17/150 (11.33%)	2/50 (4%) Mean 11.33%	10/50 (20%) SD 8.08%
#Uterus: Sarcoma Stromal			1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence		Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 347

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female					
#Uterus: Sarcoma Stromal or Po	lyp Stromal								
Overall Incidence					Total	6/50 (12%) 19/150 (12.67%)	3/50 (6%) Mean 12.67%	10/50 (20%) SD 7.02%	
#Uterus: Schwannoma Malignan									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Vagina: Polyp			•••••	•••••					
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Vagina: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Zymbal's Gland: Adenoma									
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Zymbal's Gland: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Page: 348

Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

			Male		Female			
#Zymbal's Gland: Carcinoma or Adenoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/30 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied